

## § 524.1484j

corneal ulcers. They should not be used until infection is under control and corneal regeneration is well underway. Incomplete response or exacerbation of corticosteroid responsive lesions may be due to the presence of nonsusceptible organisms or to prolonged use on antibiotic-containing preparations resulting in overgrowth of nonsusceptible organisms, particularly *Monilia*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.<sup>1</sup>

[43 FR 40456, Sept. 12, 1978]

## § 524.1484j [Reserved]

### § 524.1484k Neomycin sulfate, prednisolone, tetracaine, and squalane topical-otic suspension.

(a) *Specifications*. Each milliliter of suspension contains 5 milligrams neomycin sulfate (equivalent to 3.5 milligrams neomycin base), 2 milligrams prednisolone, 5 milligrams tetracaine, and 0.25 milliliter squalane.

(b) *Sponsor*. See 017030 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. 2 to 3 applications daily or as needed.

(2) *Indications for use*. Indicated for use in dogs and cats for treating acute otitis externa and as adjunctive therapy in management of chronic otitis externa. The product may also be used for treating moist dermatitis in dogs.

(3) *Limitations*. Tetracaine and neomycin have the potential to sensitize. If signs of irritation or sensitivity develop, discontinue use. Prolonged use of this product may result in overgrowth of nonsusceptible organisms. If new infections due to bacteria or fungi appear during therapy, appropriate measures should be taken. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 5265, Feb. 4, 1983; 48 FR 8055, Feb. 25, 1983]

### § 524.1580 Nitrofurazone ophthalmic and topical dosage forms.

#### § 524.1580a [Reserved]

#### § 524.1580b Nitrofurazone ointment.

(a) *Specifications*. The drug contains 0.2 percent nitrofurazone in a water-soluble base.

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(b) *Sponsor*. For use on dogs, cats, or horses, see Nos. 000010, 000069, 023851, 050749, 051259, 058005, and 061623 in § 510.600(c) of this chapter. For use on dogs and horses, see No. 017135 in § 510.600(c) of this chapter. For use on horses, see No. 017153 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Indications for use*. For prevention or treatment of surface bacterial infections of wounds, burns, and cutaneous ulcers of dogs, cats, or horses.<sup>1</sup>

(2) *Limitations*. Apply directly on the lesion with a spatula or first place on a piece of gauze. Use of a bandage is optional. The preparation should remain on the lesion for at least 24 hours. The dressing may be changed several times daily or left on the lesion for a longer period. For use only on dogs, cats, and horses (not for food use). In case of deep or puncture wounds or serious burns, use only as recommended by veterinarian. If redness, irritation, or swelling persists or increases, discontinue use; consult veterinarian.<sup>1</sup>

[46 FR 43402, June 27, 1980, as amended at 49 FR 6476, Feb. 22, 1984; 50 FR 49373, Dec. 2, 1985; 52 FR 18691, May 19, 1987; 53 FR 32610, Aug. 26, 1988; 53 FR 40728, Oct. 18, 1988; 54 FR 29544, July 13, 1989; 54 FR 37097, Sept. 7, 1989; 55 FR 8462, Mar. 8, 1990; 55 FR 20455, May 17, 1990; 56 FR 37473, Aug. 7, 1991; 56 FR 50653, Oct. 8, 1991; 59 FR 33197, June 28, 1994; 60 FR 55659, Nov. 2, 1995; 62 FR 35077, June 30, 1997; 66 FR 14074, Mar. 9, 2001; 68 FR 4915, Jan. 31, 2003; 68 FR 36913, June 20, 2003; 69 FR 47362, Aug. 5, 2004]

### § 524.1580c Nitrofurazone soluble powder.

(a) *Specifications*. The drug contains 0.2 percent nitrofurazone in a water-soluble base.

(b) *Sponsor*. See Nos. 000010, 000069, and 050749 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. Apply several times daily to the lesion or affected area from the plastic squeeze bottle.

(2) *Indications for use*. For prevention or treatment of surface bacterial infections of wounds, burns, skin ulcers, and abscesses after incision.<sup>1</sup>

(3) *Limitations*. In case of deep or puncture wounds or serious burns, use only as recommended by veterinarian.